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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,166

12/02/2005

Gerd Seibold

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04/27/2010

WORKMAN NYDEGGER  
1000 EAGLE GATE TOWER,  
60 EAST SOUTH TEMPLE  
SALT LAKE CITY, UT 84111

EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

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04/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,166	<b>Applicant(s)</b> SEIBOLD ET AL.	
	<b>Examiner</b> Eric Blatt	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17,19-21 and 24-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-17,19-21 and 24-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 8, 11, 13-16, 19-21, 24, 30-35, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 2003/0055455) in view of Chanduszko (US 7,431,729).

Yang teaches a device for sealing a puncture (Figure 11) comprising first and second discs and a joint 162, 166 releasably coupling the discs wherein the first disk has a retracted delivery configuration and an expanded deployed configuration in which the first disk is adapted to engage with and substantially conform to the interior vessel surface, and the second disc has a retracted delivery configuration and a retracted deployed configuration configured to engage the tissue proximal to the interior vessel surface. (See Figures 4-6. If the device is deployed in a vessel puncture having tissue proximal to the interior vessel surface, the second disc will remain in a relatively retracted configuration.) The first disk is capable of being released from engagement with the interior vessel surface since this would merely require moving the first disk proximally before it is coupled to the second disk. The first disk is attached to a nut 162 and the second disk is attached to a bolt 166. The nut may be releasably coupled to the

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bolt. There is a delivery shaft 42, 144 configured to facilitate coupling of the first disk to the second disk. (Paragraph 46) The delivery shaft 42, 144 has an element 78 that engages a slot 76 on the bolt to enable controlled rotation of the bolt relative to the nut. Although a complementary element for engaging a keyway on the nut is not shown in the disclosure, it would have been obvious to provide a similar engagement structure between the shaft 42, 144 and the nut in order to allow the nut to be held in place as the bolt is rotated. Since the delivery shaft 144 controls rotation of the bolt relative to the nut, it may also be used to decouple the first disk from the second disk.

Yang does not disclose the claimed disk structure wherein the disks comprise self-expanding wire frames having petals directly connected to the joints and a biodegradable membrane encasing the frames. Chanduszko teaches a similar sealing device having two disks wherein the disks comprise self-expanding wire frames having petals directly connected to the joints and a biodegradable membrane encasing the frames. (Figures 6A-7, 12, Paragraph 64) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disks of Yang by providing the disks such that they comprise self-expanding wire frames having petals directly connected to the joints and a biodegradable membrane encasing the frames since Chanduszko teaches that this was a known sealing disk construction and the substitution would not have produced unexpected results.

Claims 7, 9, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 2003/0055455) in view of Chanduszko (US 7,431,729) as applied to claims 1 and 30 and further in view of Shaw (US 6,080,182).

Yang and Chanduszko teach all elements of claims 7 and 36 as previously discussed except for the proximal element comprising a spring. Shaw teaches a similar sealing device comprising a first disk that connects to a proximal element wherein the proximal element comprises a spring. (Figure 40D) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Yang by providing the second disk such that it has the spring-like structure of the proximal element shown in Figure 40D of Shaw since this was a known construction for the proximal element of a sealing device and the substitution would not have produced unexpected results.

Yang and Chanduszko teach all elements of claims 9 and 39 as previously discussed except for at least one delivery element being constrained to translate a maximum distal depth. Shaw discloses a related system having at least one delivery element constrained to translate a maximum distal depth. (Figure 36, Column 17, Lines 16-30) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Yang by providing a delivery element constrained to translate a maximum distal depth in order to provide a mechanical indication to a physician that the sealing device has been pushed out of the delivery catheter as taught by Shaw.

Claims 10 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 2003/0055455) in view of Chanduszko (US 7,431,729) as applied to claims 1 and 30 and further in view of Stevens et al.. (US 5,855,614).

Yang and Chanduszko teach all elements of claims 10 and 37 as previously discussed except for one or both of the first disk and the proximal element comprising barbs, hooks, sharp edges, or roughened surfaces. Stevens discloses a related sealing device wherein the first disk and the proximal element comprise barbs, hooks, sharp edges, or roughened surfaces. (Figures 10-15, Column 20, Lines 27-48) It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Yang et al by providing barbs, hooks, or sharp edges to aid the closure device in engaging the vessels walls as taught by Stevens.

Claims 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 2003/0055455) in view of Chanduszko (US 7,431,729) as applied to claims 1 and 14 above, and further in view of Van Tassel et al et al (US 6,949,113).

Yang and Chanduszko teach all elements of claims 12 and 17 as previously discussed except for a coagulant-enhancing agent being disposed on one or both of the first disk and the proximal element. Van Tassel et al discloses device for sealing an opening in a blood vessel comprising a coagulant-enhancing agent that is disposed on a disk. (Column 12, Lines 20-24) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Yang et al by providing a coagulant-enhancing agent that is disposed on one or both of the first disk and the

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proximal element to prevent blood from passing through the sealed puncture as taught by Van Tassel et al.

### ***Response to Arguments***

Applicant's arguments filed 1-21-2010 have been fully considered but they are not persuasive. Applicant's arguments merely consist of assertions that the cited references fail to disclose or suggest the newly added claim recitations with regard to the expanded/deployed configurations of the first disk and the proximal member and the driving means of the delivery apparatus. As explained in the body of the rejection, it is the Examiner's position that Yang does indeed teach these features.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735.

The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Blatt/  
Examiner, Art Unit 3734

/TODD E. MANAHAN/  
Supervisory Patent Examiner, Art Unit 3734